REMARKS

Claims 1, 3, 6, 8 and 11 and 13-17 are pending in this application. By this Amendment, claims 1, 6 and 11 are amended, new claims 13-17 are added, and claims 4, 5, 9, 10 and 12 are canceled without prejudice to, or disclaimer of, the subject matter recited therein. Support for the amendments and the new claims can be found, for example, in the specification (see paragraphs [0023], [0024], [0025], [0026], [0036], [0037] and Example 1). No new matter is added.

Applicants appreciate the courtesies shown to Applicants' representative by Examiners Young and Jones in the November 30, 2009 personal interview. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

In view of the foregoing amendments and the following remarks, reconsideration and allowance of the claims are respectfully requested.

I. Objection to the Claims

The Office Action objects to claims 1, 6, 11 and 12 due to informalities. By this Amendment, claim 12 is canceled. Thus, the objection as to that claim is moot. As to the remaining claims, Applicants respectfully traverse the objection. By this Amendment, claims 1, 6 and 11 are amended to obviate the objection. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

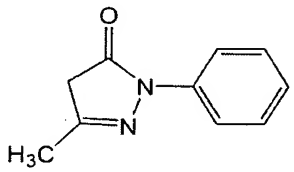
II. Rejection Under 35 U.S.C. §112

The Office Action rejects claims 1 and 6 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. By this Amendment, claims 1 and 6 are amended to obviate the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1, 3-6 and 8-12 under 35 U.S.C. §103(a) over JP 10-279480 to Uchiumi et al. ("Uchiumi") in view of JP 10-265373 to Koide et al. ("Koide") and EP 1 174 132 to Mori et al. ("Mori"). By this Amendment, claims 4, 5, 9, 10 and 12 are canceled, rendering the rejection moot as to those claims. As to the remaining claims, Applicants respectfully traverse the rejection.

Claim 1 recites:

> A percutaneous absorption preparation containing 3-methyl-1-phenyl-2-pyrazolin-5-one, wherein it contains, as an active ingredient, 0.1 to 30 percent by mass of 3-methyl-1-phenyl-2-pyrazolin-5-one represented by the following formula:
>
> 
>
>
> or a medically acceptable salt thereof in an aqueous base wherein the aqueous base comprises: a water-soluble polymer selected from the group consisting of sodium polyacrylate, starch acrylate and methyl acrylate/acrylic acid 2-ethylhexyl copolymer resin emulsion; a cross-linking agent; and a polyhydric alcohol and water.

Uchiumi, Koide and Mori, in any combination, would not have rendered obvious the above features of claim 1.

As discussed during the November 30 interview and acknowledged by the Office Action, Uchiumi fails to disclose specific concentration amounts of the carrier formulation and is not directed to a percutaneous composition, as recited in claim 1 (Office Action, page 3). Uchiumi merely discloses a drug formulation as a divided dose of 3-methyl-1-phenyl-2-pyrazolin-5-one ("EDV") including: (1) 1-100 mg for oral administration; (2) 0.01-50 mg for intravenous injection; and (3) 1-100 mg for intrarectal administration (Uchiumi, Abstract).

The Office Action applies Koide and Mori to allegedly remedy the deficiencies of Uchiumi. The Office Action asserts that Koide and Mori disclose various features of claim 1 including specific dosage percentages of active agents, but acknowledges that Koide and Mori fail to disclose the specific active agent 3-methyl-1-phenyl-2-pyrazolin-5-one, as recited in claim 1 (Office Action, pages 4-5). The Office Action asserts that it would have been allegedly obvious to one of ordinary skill in the art include the compound of Uchiumi into the dosage percentages of Koide or Mori and that the formulation of Koide is "similar enough" to the instant claims that any modifications would have been allegedly obvious as a result of routine experimentation (Office Action, page 5). However, for at least the reasons presented below, Uchiumi, Koide and Mori would not have rendered obvious the above features of claim 1.

As discussed during the interview, Applicants hereby submit a Declaration Under 37 C.F.R. §1.132 ("Declaration") of Jun Mori with experimental tests directed to comparative compositions of Koide and Mori. With respect to Koide, comparative tests directed to Example 3 of Koide are included in the Declaration, selected as the composition demonstrating the highest adhesion of that reference. With respect to Mori, comparative tests directed to Examples 3 and 4 are included in the Declaration, as compositions closest to the percutaneous absorption preparation recited in claim 1. For the Examiner's convenience, Applicants also hereby submit an English-language translation of Tables 1-5 of Koide, for reference with respect to the Declaration.

The Declaration describes experimental tests that were performed to measure and observe the formability, adhesiveness, and skin transmission properties of: (1) Preparation A, a percutaneous absorption preparation according to Example 1 of the specification; (2) Preparations B and C, two adhesive preparations according to Example 3 of Koide, where C is similar to B except that 52.75 parts of pure H_2O were used in place of 3 parts EDV and 49.75 parts pure H_2O; (3) Preparations D and E, two absorption preparations according to

Example 3 of Mori, where E is similar to D except that no EDV was added; and (4) Preparations F and G, two absorption preparations according to Example 4 of Mori, where G is similar to F except that no EDV was added (see specification, paragraphs [0038] and [0039]; Koide, Table 1; and Mori, paragraphs [0050] and [0051]). Skin transmission property tests identical to those disclosed in the specification were conducted on each of Preparations A-G (specification, paragraph [0042]).

As shown in Table 1, the Declaration clearly shows that the percutaneous absorption preparation recited in claim 1 has unexpectedly superior formability, adhesiveness and skin transmission properties relative to the comparative preparations of Koide and Mori. More specifically: (1) the skin transmission property of Preparations B and C **decreased by approximately 31.4%**; (2) the skin transmission property of Preparations D and E **decreased by approximately 67.6%**; and (3) the skin transmission property of Preparations D and E **decreased by approximately 21.5%** when compared to Preparation A, as recited in claim 1. None of the applied references provide any reason or rationale for one of ordinary skill in the art to have expected that the percutaneous absorption preparation recited in claim 1 would have yielded the vastly improved results shown in the Declaration.

In view of the foregoing, Applicants respectfully submit that the percutaneous absorption preparation of claim 1 would not have been rendered obvious by Koide, Mori and Uchiumi, at least because the evidence presented herewith establishes that the preparation of claim 1 possess improved and unexpected properties relative to the alleged disclosures of the applied references. The remaining claims variously depend from claim 1 and, thus, also would not have been rendered obvious by Koide, Mori and Uchiumi for at least the reasons set forth above.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Double Patenting

The Office Action provisionally rejects claims 1, 3-6 and 8-10 under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of copending Application No. 10/579,055. Without admitting to the propriety of the rejection, and in the interest of advancing prosecution, Applicants are simultaneously filing herewith a Terminal Disclaimer over the cited reference, thus, obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. New Claims

By this Amendment, new claims 13-17 are added. New claims 13-17 depend from claim 1 and, thus, distinguishes over the applied references for at least the reasons discussed above with respect to claim 1, as well as for the additional features they recite.

Prompt examination and allowance of new claims 13-17 are respectfully requested.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

James A. Oliff
Registration No. 27,075

Sarah Lhymn
Registration No. 65,041

JAO:SQL/hs

Attachments:
English-language translation of Tables 1-5 of JP 10-265373 to Koide et al.
Declaration Under 37 C.F.R. §1.132
Terminal Disclaimer over co-pending U.S. Patent Application No. 10/579,055
Petition for Extension of Time

Date: March 3, 2010

OLIFF & BERRIDGE, PLC
P.O. Box 320850
Alexandria, Virginia 22320-4850
Telephone: (703) 836-6400

DEPOSIT ACCOUNT USE AUTHORIZATION
Please grant any extension necessary for entry of this filing; Charge any fee due to our Deposit Account No. 15-0461

Table 1

Example No .	1	2	3	4
(a) Polyacrylic acid (average molecular weight: 150,000)	4.0	4.0	4.0	4.0
(b) Polyacrylic acid (average molecular weight: 1,000,000)	-	-	-	-
(c) Gelatin	-	-	-	-
(d) Sodium polyacrylate	1.5	1.5	1.5	1.5
(e) Sodium carboxymethyl cellulose (1,500 cps)	-	-	-	-
(f) Sodium carboxymethyl cellulose (7,000 cps)	-	-	-	-
(g) Polyvinyl alcohol	1.0	1.0	1.0	1.0
(h) Glycerin	15.0	15.0	15.0	15.0
(i) Sorbitol	10.0	10.0	10.0	10.0
(j) Glycine	-	0.1	0.1	0.1
(k) Synthetic hydrotalcite	0.05	0.05	0.05	0.05
(l) Alminum glycinate	0.1	-	-	-
(m) Alminum hydroxide	-	0.1	-	-
(n) Magnesium metasilicate aluminate	-	-	0.1	-
(o) Magnesium silicate aluminate	-	-	-	0.1
(p) Polyoxyethylene glycol ether	1.0	1.0	1.0	1.0
(q) Kaolin	6.0	6.0	6.0	6.0
(r) NIKKOL MYL-10	1.5	1.5	1.5	1.5
(s) Castor oil	1.0	1.0	1.0	1.0
(t) Propylene glycol	3.0	3.0	3.0	3.0
(u) 1,3-Butylene glycol	-	-	3.0	-
(v) Pure water	balance	balance	balance	balance
(w) Ball Number (adhesion)/Workability*	20/o	18/o	24/o	21/o

Example No.	5	6	7	8	9	10	11	12	13
(a)	4.0	4.0	4.0	-	-	-	-	-	-
(b)	-	-	-	-	-	-	-	-	-
(c)	-	-	-	-	-	-	-	-	-
(d)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(e)	-	-	-	4.0	4.0	4.0	4.0	4.0	4.0
(f)	-	-	-	-	-	-	-	-	-
(g)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(h)	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
(i)	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
(j)	0.1	0.1	0.1	-	-	-	-	-	-
(k)	-	-	-	0.05	0.05	0.05	0.05	-	-
(l)	0.1	0.1	0.1	0.1	-	-	-	0.1	0.1
(m)	0.1	-	-	-	0.1	-	-	0.1	-
(n)	-	0.1	-	-	-	0.1	-	-	0.1
(o)	-	-	0.1	-	-	-	0.1	-	-
(p)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(q)	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
(r)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(s)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(t)	-	-	-	-	-	-	-	-	-
(u)	3.0	3.0	3.0	3.0	3.0	3.0	3.0	-	-
(v)	balance	balance	balance	balance	balance	balance	balance	balance	balance
(w)	21/o	17/o	21/o	18/o	22/o	18/o	19/o	20/o	23/o

Example No.	14	15	16	17	18	19	20	21
(a)	-	2.0	2.0	2.0	2.0	2.0	2.0	2.0
(b)	-	-	-	-	-	-	-	-
(c)	-	-	-	-	-	-	-	-
(d)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(e)	4.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
(f)	-	-	-	-	-	-	-	-
(g)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(h)	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
(i)	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
(j)	-	-	0.1	0.1	0.05	0.1	0.1	0.1
(k)	-	0.05	0.05	0.05	-	-	-	-
(l)	0.1	0.1	-	-	-	0.1	0.1	0.1
(m)	-	-	0.1	-	-	0.1	-	-
(n)	-	-	-	0.1	-	-	0.1	-
(o)	0.1	-	-	-	0.1	-	-	0.1
(p)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(q)	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0
(r)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(s)	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(t)	3.0	3.0	3.0	3.0	-	-	-	-
(u)	-	-	3.0	-	3.0	3.0	3.0	3.0
(v)	balance	balance	balance	balance	balance	balance	balance	balance
(w)	20/o	17/o	24/o	21/o	18/o	22/o	22/o	19/o

Example No.	22	23	24	25	26	27	28
(a)	-	-	-	-	-	-	2.0
(b)	-	-	-	-	-	1.0	-
(c)	3.0	3.0	3.0	3.0	3.0	2.0	2.0
(d)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(e)	-	-	-	-	-	-	-
(f)	-	-	-	-	-	-	-
(g)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(h)	15.0	15.0	15.0	15.0	15.0	15.0	15.0
(i)	10.0	10.0	10.0	10.0	10.0	10.0	10.0
(j)	-	0.1	0.1	0.05	0.1	0.1	0.1
(k)	0.05	0.05	0.05	-	-	-	0.1
(l)	0.1	-	-	-	0.1	0.1	0.1
(m)	-	0.1	-	-	0.1	-	-
(n)	-	-	0.1	-	-	0.1	-
(o)	-	-	-	0.1	-	-	-
(p)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(q)	6.0	6.0	6.0	6.0	6.0	6.0	6.0
(r)	1.5	1.5	1.5	1.5	1.5	1.5	1.5
(s)	1.0	1.0	1.0	1.0	1.0	1.0	1.0
(t)	3.0	3.0	3.0	-	-	-	-
(u)	-	3.0	-	3.0	3.0	3.0	3.0
(v)	balance	balance	balance	balance	balance	balance	balance
(w)	22/o	20/o	19/o	19/o	22/o	18/o	20/o

Example No.	29	30	Comparative Example No.	1	2	3	4	5
(a)	-	1.0		4.0	-	-	-	-
(b)	-	1.0		-	4.0	-	-	-
(c)	2.0	1.0		-	-	4.0	-	-
(d)	1.5	1.5		1.5	1.5	1.5	1.5	1.5
(e)	2.0	1.0		-	-	-	4.0	-
(f)	-	-		-	-	-	-	4.0
(g)	1.0	1.0		1.0	1.0	1.0	1.0	1.0
(h)	15.0	15.0		15.0	15.0	15.0	15.0	15.0
(i)	10.0	10.0		10.0	10.0	10.0	10.0	10.0
(j)	0.1	0.1		-	-	-	-	-
(k)	0.1	0.1		-	-	-	-	-
(l)	0.1	0.1		-	-	-	-	-
(m)	-	-		-	-	-	-	-
(n)	-	-		-	-	-	-	-
(o)	-	-		-	-	-	-	-
(p)	1.0	1.0		1.0	1.0	1.0	1.0	1.0
(q)	6.0	6.0		6.0	6.0	6.0	6.0	6.0
(r)	1.5	1.5		1.5	1.5	1.5	1.5	1.5
(s)	1.0	1.0		1.0	1.0	1.0	1.0	1.0
(t)	-	-		3.0	-	-	-	-
(u)	3.0	3.0		3.0	3.0	3.0	3.0	3.0
(v)	balance	balance		balance	balance	balance	balance	balance
(w)	17/o	18/o		8/o	9/x	10/x	10/x	8/x

* Workability was evaluated as follows: in case where the composition can be uniformly extended on non-woven fabric or film, workability was evaluated as "o", and in case where the composition cannot be uniformly extended on non-woven fabric or film, workability was evaluated as "x".